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Operator's manual

IMPORTANT:

Please read this operator's manual carefully before using the BPro®.

Authorized agent:



BPro®

Radial Pulse Wave Acquisition Device

BPro[®]

Radial pulse wave acquisition device



Operator's manual

IMPORTANT:

Please read this operator's manual carefully before using the BPro.

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Introduction

The **BPro® radial pulse wave acquisition device** is based on arterial tonometry at the radial artery of the wrist. It can be used as part of the **BPro® ambulatory blood pressure monitoring (ABPM) system**, the **A-PULSE CASP® pulse wave analysis system**, or the **BProSoftCASP® 24-Hour Ambulatory BP/CASP Monitoring System**.

The **BPro® ABPM system** consists of the **BPro® radial pulse wave acquisition device**, a blood pressure (BP) calibrator and the **BProSoft® 24-hour ABPM application software**. The **BPro®** is used to capture the pulse wave from the radial artery, and the BP calibrator is used to calibrate the **BPro®** before each ABPM session. Once calibrated, the **BPro®** is capable of recording up to 96 readings of systolic and diastolic blood pressure and pulse rate over a period of 24 hours. The BProSoft software communicates with the **BPro®** to retrieve, analyze, display and print ABPM data.

The **A-PULSE CASP® pulse wave analysis system** consists of the **BPro® radial pulse wave acquisition device**, a BP calibrator and the **A-PULSE CASP® pulse wave application software**. The **BPro®** is used to capture the pulse wave from the radial artery, and the BP calibrator is used to calibrate the pulse wave. Once the pulse wave is calibrated, the software is used to derive the central aortic systolic pressure, radial augmentation index (rAI) and a range of other pulse wave indices. The software allows the pulse wave, blood pressure readings and pulse rate readings to be displayed, stored and printed.

The **BProSoftCASP® 24-Hour Ambulatory BP/CASP Monitoring System** consists of the **BPro® radial pulse wave acquisition device**, a BP calibrator and the **BProSoftCASP® 24-Hour Ambulatory BP/CASP application software**. The **BPro®** is used to capture the pulse wave from the radial artery, and the BP calibrator is used to calibrate the pulse wave. Once the pulse wave is calibrated, the software is used to derive the central aortic systolic pressure, radial augmentation index (rAI) and a range of other pulse wave indices. The software allows the pulse wave, blood pressure readings and pulse rate readings to be displayed, stored and printed.

The **MC3000™** or **MC3100™ oscillometric blood pressure monitor**, or an equivalent, may be used as the BP calibrator.

This manual focuses on the **BPro® radial pulse wave acquisition device**. For information on the use of the **BProSoft®, A-PULSE CASP® and BProSoftCASP® 24-Hour Ambulatory BP/CASP application software**, refer to their respective manuals.

Intended Use and Indications for use














The **BPro®** radial pulse wave acquisition device is intended for use with the BP calibrator and **BProSoft® 24-hour ABPM application software** to measure systolic pressure, diastolic pressure and pulse rate over a period of 24 hours.

The **BPro®** radial pulse wave acquisition device is also intended for use with the BP calibrator and **A-PULSE CASP® pulse wave application software** to derive the central aortic systolic pressure, radial augmentation index (rAI) and a range of other indices from the radial pulse.

The **BPro®** radial pulse wave acquisition device is also intended for use with the BP calibrator and **BProSoftCASP® 24-Hour Ambulatory BP/CASP application software** to manage 24-hour ambulatory blood pressure (BP) and central aortic systolic pressure (CASP), and to retrieve, analyze, display and print ABPM report.

For both applications, the **BPro®** is intended for use on patients who are eighteen (18) years or older, have a palpable radial pulse, and do not have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation. The results are intended for use by qualified healthcare personnel as an aid to diagnosis and treatment.

Symbols

No.	Symbol	Description
1		This product complies with the European Council Directive 93/42/EEC (Medical Device Directive).
2		Type BF: Device (applied part) is designed to provide special protection against electrical shock
3		See accompanying documents or see instructions for use
4		Caution
5		Date of manufacture
6		Manufacturer
7		Authorized representative in the European Community
8		Dispose of this product and used batteries in accordance with the national regulations for the disposal of electrical products.
9		Prohibited action
10		Important information to note
11		Use by
12		Lot number
13		This product and its package do not contain natural rubber latex.
14	PN	Part number
15	SN	Serial number

Precautions for use

Precautions

- **DO** read this operator's manual thoroughly before using the BPro. For additional precautions refer to the BP calibrator instruction manual
- **DO** calibrate the BPro before every ABPM session.
- **DO** keep the wrist still for about 12–15 seconds during measurements for optimal results.
- **DO** try to keep a safe distance of 0.5 to 1 meter (1.6 to 3.3 ft) between the BPro and sources of electromagnetic radiation such as microwave oven, television or mobile phones when measuring blood pressure. For more details, refer to the manufacturer's EMC declaration in this manual.
- **DO NOT** apply the BPro to injured or irritated skin.
- **DO NOT** subject the BPro to extreme temperatures, humidity or direct sunlight.
- **DO NOT** subject the BPro to strong shocks, such as dropping it on the floor.
- **DO NOT** immerse the BPro in water. The BPro is mildly water-resistant (IPX2). Use a dry cloth to wipe the BPro if it gets wet.
- **DO NOT** immerse the BPro in cleaning solution. Follow the recommended cleaning instructions in this manual.
- **DO NOT** attempt to disassemble, service or repair the BPro. Contact HealthSTATS or an authorized agent if a problem occurs. Follow the recommended instructions for replacement of the fastening strap.
- **DO NOT** use the BPro with defibrillators. Remove the BPro before using a defibrillator.
- **DO NOT** use the BPro in the presence of electrosurgery.
- **DO NOT** use the BPro for monitoring of blood pressure during exercise or any vigorous activity.
- **DO NOT** leave the BPro in the "Std by" mode for an extended period of time so as to reduce battery power consumption. Switch back to the time/date mode when the BPro is not in use.

Points to note

- A qualified physician should be consulted for diagnosis and interpretation of the blood pressure patterns and other results obtained with the BPro.
- The BPro is suitable for use on adults with wrist circumference ≥ 13 cm. It is not suitable for use on children or patients with wrist circumference < 13 cm.
- Blood pressure measurements using the BPro are based on calibration to the patient's unique pulse waveform. Calibration is required before every ABPM session.
- A person's blood pressure fluctuates over a 24-hour period and the BPro will automatically measure blood pressure at regular preset intervals. Readings are stored in the memory of the BPro and may be later downloaded to a computer using the BProSoft software.
- For patients in shock, noninvasive methods of measuring blood pressure may not be reliable because of peripheral vascular changes. Invasive measurement should be considered for patients with signs of shock or whose blood pressure is unstable.

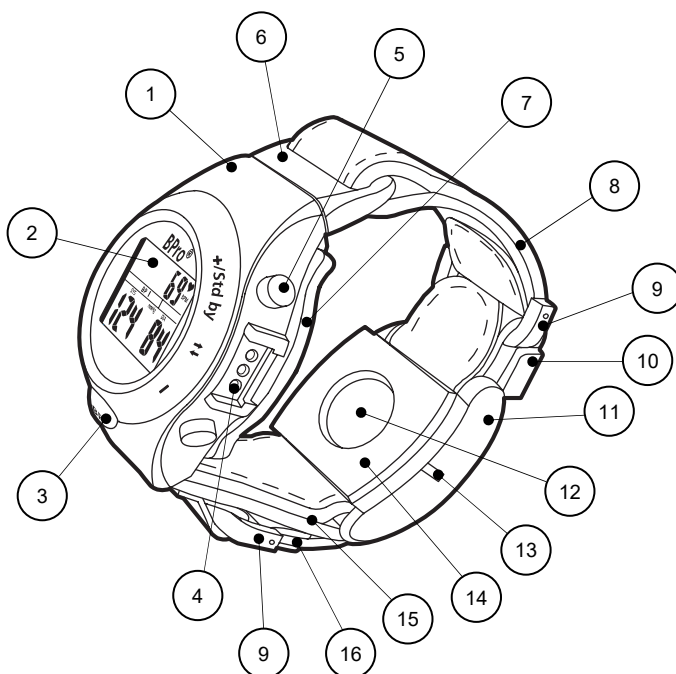
- As with the manual auscultatory method, it is not always possible to obtain accurate noninvasive readings under certain conditions. Factors such as patient movement, incorrect positioning of the cuff relative to the heart level, extreme heart rates and arrhythmias can lead to inaccurate measurements. Vibrations, such as those in a moving vehicle, can also lead to inaccurate measurements.
- Excessive motion during a measurement cycle may affect the accuracy of the measurement. Three audible beeps are provided to alert the patient to a new measurement cycle and to remind the patient to keep the wrist still.
- An event code will be recorded by the BPro whenever it is unable to provide valid blood pressure readings for a measurement cycle even after repeated attempts. The event code will appear on the ABPM report.


Unpacking your BPro package

Ensure that you have all the necessary items in your BPro package. Refer to the components list provided separately.


Features and functions of the BPro

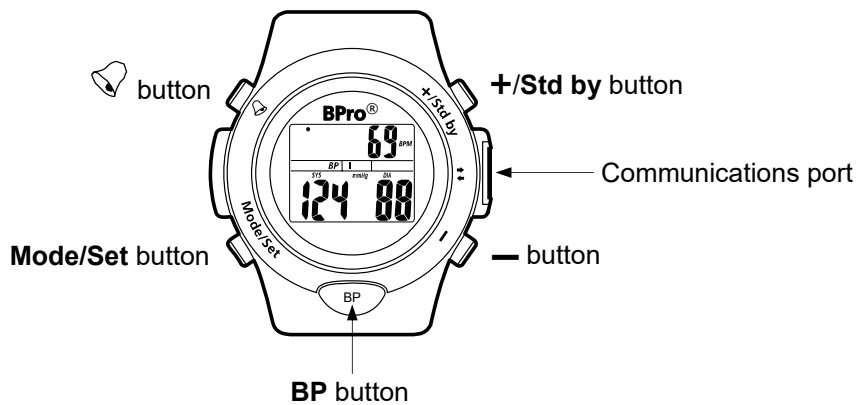
Identification of parts






- | | |
|--|------------------------------|
| 1 LCD housing | 9 C-bracket |
| 2 Backlit LCD | 10 Strap loop |
| 3 BP button | 11 Sensor housing |
| 4 Communications port | 12 Sensor plunger |
| 5 Control button | 13 Sensor positioning marker |
| +/- Std by, — , Mode/Set and  | 14 Sensor case cushion |
| 6 Strap diverter | 15 Connecting strap |
| 7 Back case cushion | 16 Sensor support strap |
| 8 Fastening strap | |

Control buttons

Mode/Set	<ul style="list-style-type: none">■ Select operating mode■ Enter and exit setting mode■ Select and set parameter in setting mode
	<ul style="list-style-type: none">■ Turn audible beep alerts ON or OFF (for ABPM session only)■ Illuminate backlight for 5 seconds
+ / Std by	<ul style="list-style-type: none">■ Increase value■ Enter and exit calibration mode (Std by and rEADY)■ Select day or seconds for display■ Delete log
—	<ul style="list-style-type: none">■ Decrease value■ Display day of week and date (month and day)
BP	<ul style="list-style-type: none">■ Calibrate BPro■ Verify calibration and start ABPM session■ Terminate ABPM session



Operating modes

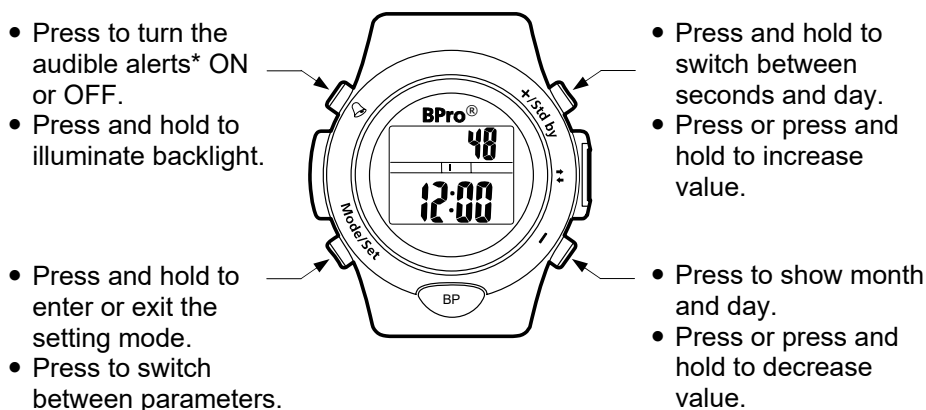
<p>Time/date mode</p> 	<ul style="list-style-type: none"> ■ Set time and date
<p>ABPM mode</p> 	<ul style="list-style-type: none"> ■ Automatically take blood pressure measurements at preset intervals over a 24-hour ABPM session ■ Store date and time stamp for every measurement ■ Indicate optimum strap tension and pulsations for blood pressure measurement ■ Calibrate BPro before starting each ABPM session ■ Enter systolic and diastolic calibration readings ■ Delete ABPM data
<p>PC Conn mode</p> 	<ul style="list-style-type: none"> ■ Download data to a computer that has BProSOft blood pressure report management software installed

Time/date mode

Time and date settings

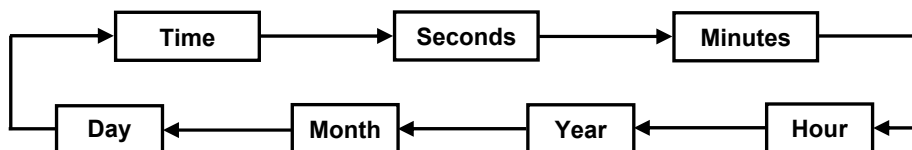
This mode allows you to set and display time and date.

1. Press and hold **+ / Std by** to set the top row to display either seconds or the day of week.
2. Press **—** to display the day of week and date (month and day) for 5 seconds.
3. Press and hold **Mode/Set** to enter the time/date parameter setting mode. The selected parameter will flash.
4. Press **Mode/Set** to select the parameter to be set. Press **+ / Std by** or **—** to increase or decrease the value respectively.
5. Press and hold **Mode/Set** to exit the setting mode anytime.



**The audible alerts apply to ABPM sessions only.*

Time and date setting sequence



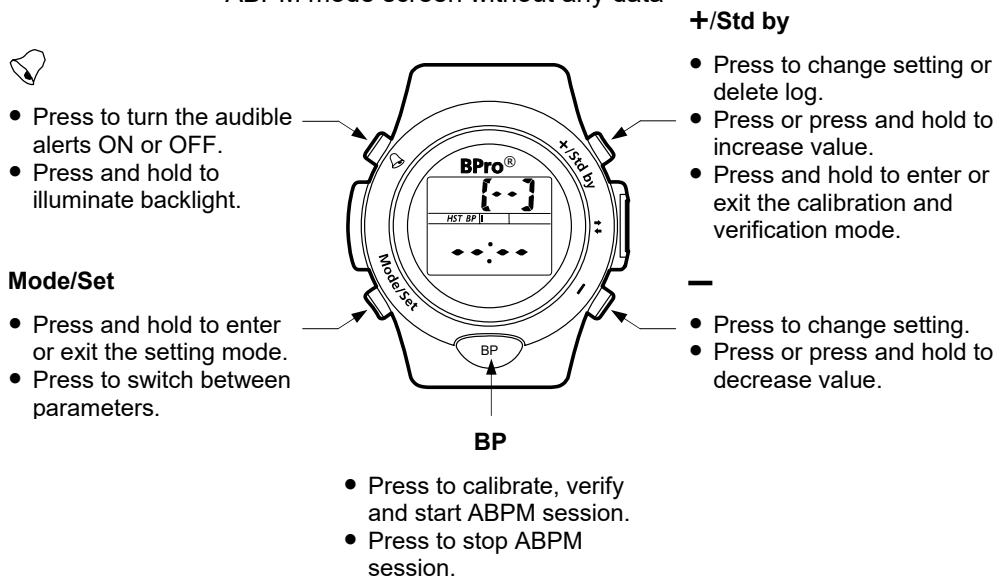
ABPM mode

ABPM mode settings

This mode allows you to set or change parameter settings before performing an ABPM session.


1. Press the **Mode/Set** button to select the ABPM mode.

ABPM mode screen without any data




2. Press and hold **Mode/Set** to enter the parameter setting mode. The parameters to be changed will flash.
3. Press **+ / Std by** to adjust the parameter upward, delete ABPM data, and enter the calibration and verification mode.
4. Press **—** to adjust the parameter downward.
5. Press **BP** to calibrate, verify and start or stop a 24-h ABPM session.
6. Press **Bell icon** to turn the audible alerts ON or OFF or to illuminate the backlight for 5 seconds.

ABPM mode parameters

Fixed parameters	
Interval	The measurement interval is fixed at 15 minutes. This will yield 96 measurements over 24 hours.
Sampling duration	The sampling duration of the BPro is fixed at 8 seconds. BPro will sample 8 seconds worth of data and then select valid waveforms for calculation.
Sampling rate	The sampling rate of the BPro is fixed at 60 points per second.
Period	The period for the ABPM session is fixed at 24 hours. The BPro will automatically terminate the ABPM session after 24 hours.
On-demand parameters	
Log Delete	Denoted by Log dEL . After downloading the data, you can delete them from memory and get ready for the next ABPM session. Press + / Std by to confirm the deletion and a completion message denoted by dOnE will appear.
Audible alerts	Denoted by a bell icon (). When this is ON, the icon will be displayed on the BPro.

Audible and visual alerts

Audible alerts


It is recommended that the audible alerts () be turned ON for all ABPM sessions. When this feature is ON, the audible alerts bell icon will be displayed and the BPro will provide the following audible alerts during an ABPM session:

Measurement begins	3 short beeps during ABPM session just before the BPro takes a blood pressure measurement.
Measurement repeats	1 long beep during ABPM session when the BPro needs to re-take a blood pressure measurement. May occur up to two times.
Measurement complete	1 short beep during ABPM session to indicate that the measurement is complete.

The user has the option to turn the audible alerts ON or OFF at anytime in any mode.

Visual alerts

The BPro provides a visual alert when the battery is low on power.

<p>Low battery</p> 	<p>When the low-battery symbol is displayed and flashing, the battery should be replaced. Refer to the section “Battery replacement” for more information on how to replace a battery.</p>
--	--

Starting an ABPM session

Selecting the strap length

1. Before using the BPro, measure the patient's wrist circumference using a tailor's measuring tape.
2. Select the strap length according to the table below:

Wrist circumference	Strap length
13.0 – 15.0 cm	95 mm (3.7 in.), small
15.0 – 17.0 cm	125 mm (4.9 in.), medium
17.0 – 21.0 cm	155 mm (6.1 in.), large
> 21.0 cm	185 mm (7.3 in.), extra large

A strap that is too short or too long may not adequately secure the BPro to the wrist.

3. Verify that the strap size is appropriate for the patient before using the BPro.

Taking calibration readings

Step 1

Relax for at least 10 minutes and take 5 or more slow, deep breaths.

Step 2

Take 4 measurements using the BP calibrator with the cuff wrapped around the arm on which the BPro is mounted. Record the systolic, diastolic and pulse rate readings.

Note: Ensure that the correct size is used. Allow an interval of 30 to 60 seconds between measurements. Refer to the instruction manual for the BP calibrator for details.

Step 3

Discard the first set of readings. If any two of the remaining 3 readings for systolic or diastolic pressure differ by more than 10 mmHg, take more measurements until the last 3 consecutive readings for each pressure do not differ from each other by more than 10 mmHg. Then average the 3 readings for each pressure.

Note: The average systolic and diastolic readings will be used for calibration.

Step 4

Remove the cuff from the patient and turn off the BP calibrator.

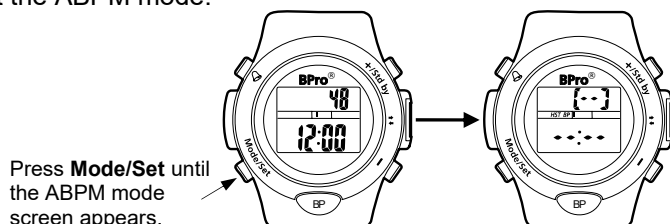
Preparing the BPro for calibration

Step 5

Ensure that the time and date on the BPro are correctly set (refer to the section "Time/date mode" for details if necessary).

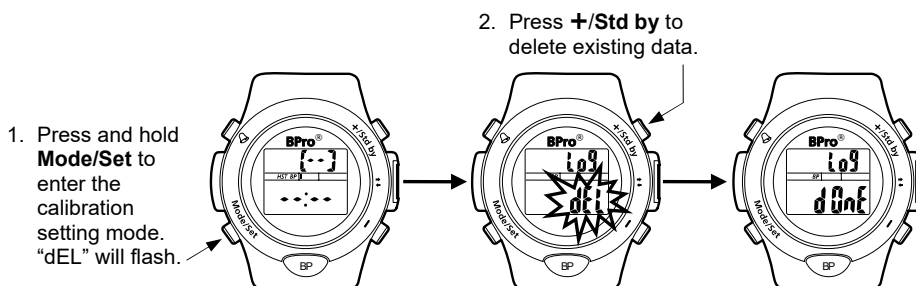
Step 6

Select the ABPM mode.



Step 7

Enter the calibration setting mode.



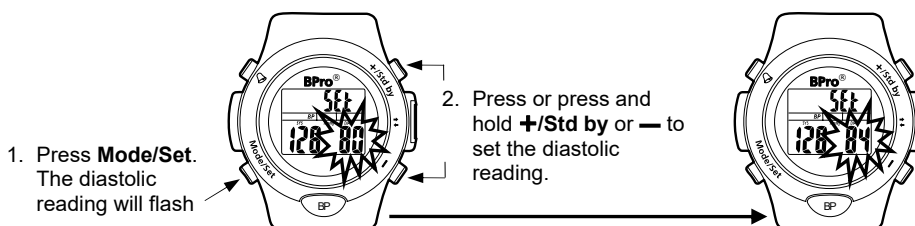
Step 8

Input the average systolic reading into the BPro.



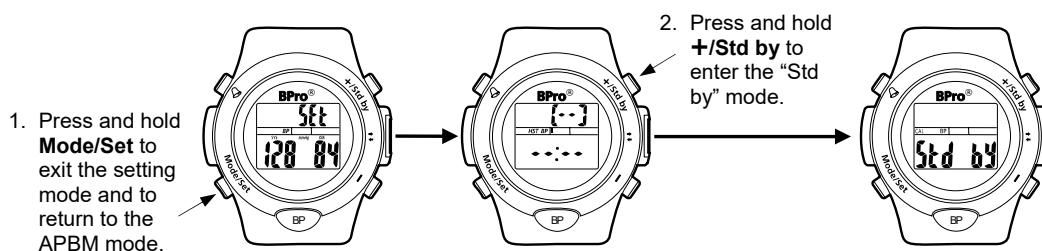
Step 9

Input the average diastolic reading into the BPro.



Step 10

Confirm your calibration readings (e.g., 124/84).



Mounting the BPro on the patient

Step 11

Place your index, middle and ring fingers on the patient's wrist to palpate the radial artery.



Note: The BPro should be mounted on the wrist of the arm from which calibration readings were taken.

Step 12

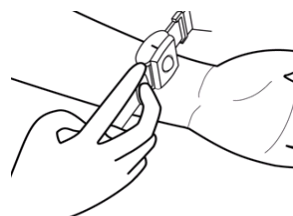
Locate the region where the radial pulse is most strongly felt, usually at the middle finger.



Step 13

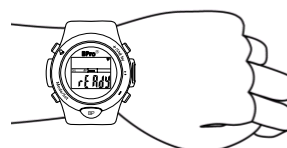
Position the sensor plunger over this region, using the white marks on both sides of the sensor housing as a guide.

Note: Before mounting the BPro, you may wish to apply *Betnovate™* cream or a similar cream on the wrist area to minimize skin irritation during the ABPM session.



Step 14

While holding the plunger in place, insert the strap through the diverter, pull on the strap and fasten the Velcro. The display will show **Std by** and then **rEAdy** if the pulsations, as indicated on the pulse indicator, are acceptable. There should be at least 4 bar segments on the indicator. If necessary, re-position the plunger or adjust the strap tension until these two messages are displayed. Remind the patient to keep the wrist still.

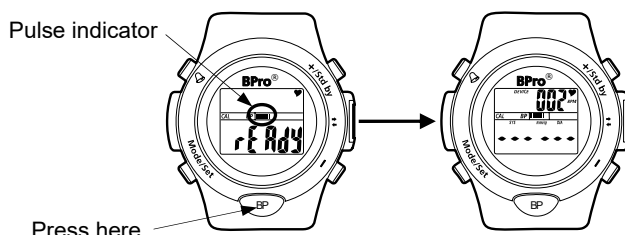


The BPro should not be strapped too tightly to the wrist. Otherwise, it may obstruct blood circulation and cause numbness to the hand. If the patient complains of numbness, loosen the straps.

Calibrating the BPro

Step 15

When the display shows **rEAdy** with constant pulsations and at least 4 bar segments on the pulse indicator, press the **BP** button to calibrate the BPro. Remember to keep the wrist still. This step will take about 12 seconds.



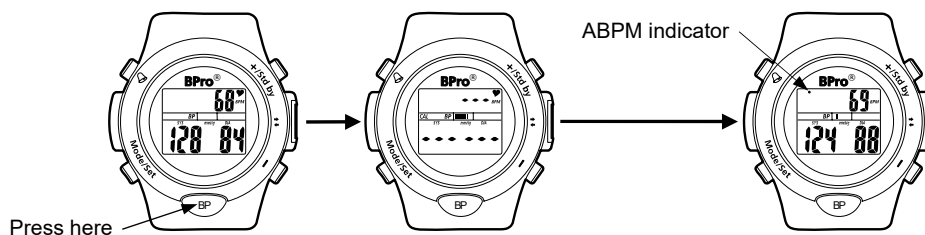
Upon successful calibration, the calibration and pulse rate readings will be displayed.

Verifying the calibration

Step 16

To verify the calibration, press the **BP** button again within 2 minutes to activate a measurement. Remember to keep the wrist still. This step will take about 12 seconds.

If the verification is successful, the pulse rate, systolic and diastolic readings will appear and the ABPM indicator (dot) will be displayed at top left corner of the LCD. The BPro will start taking the measurements at the preset interval of 15 minutes for the next 24 hours. The indicator indicates that ABPM is in progress.



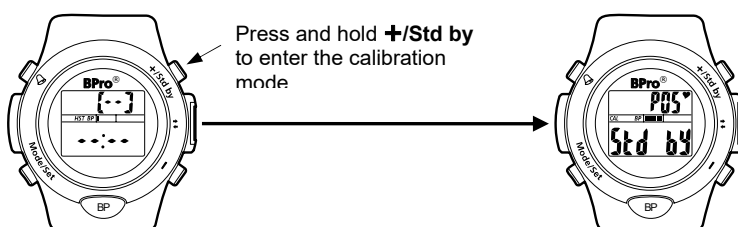
Note: This verification must be completed within 2 minutes or otherwise **CAL FAIL** will be displayed and you will need to recalibrate the BPro.

Recalibrating the BPro

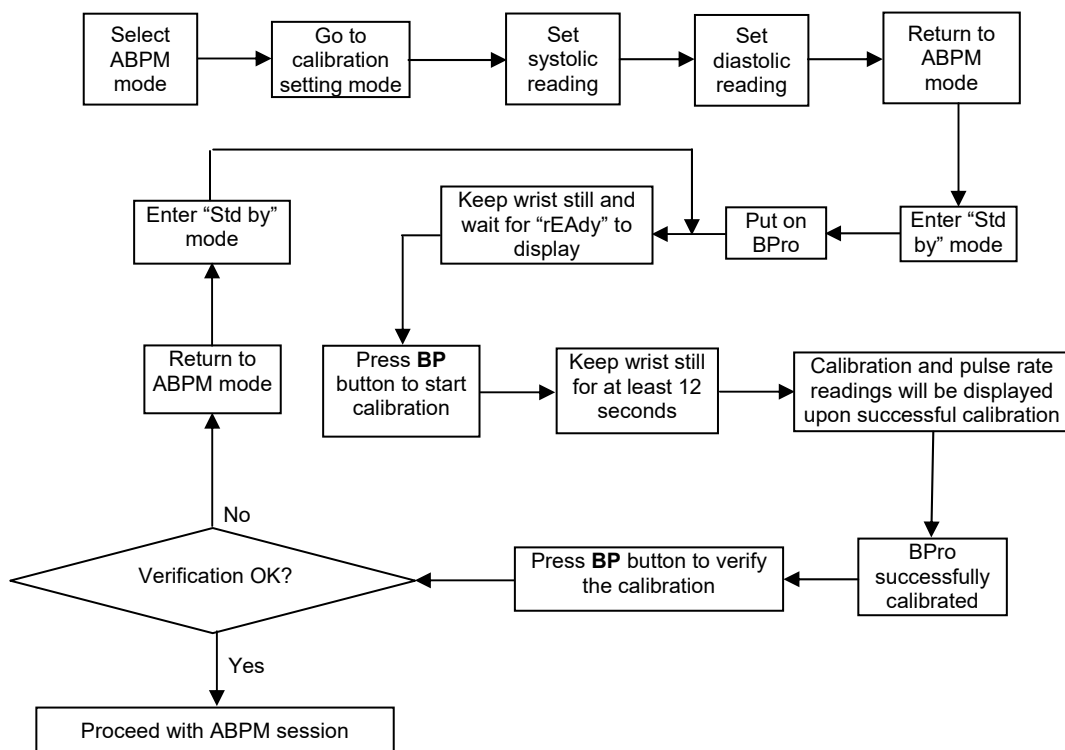
Step 17

Either of the following messages may appear on the BPro during the verification:

- **POS AdJ:** This message could have resulted from wrist motion or improper sensor position during verification. Adjust the sensor position if necessary, keep the wrist still and then press the BP button again.
- **CAL FAIL:** This message appears possibly because the readings are NOT within ± 10 mmHg of the calibration readings, which could have resulted from wrist motion or improper sensor position during verification. Adjust the sensor position if necessary and recalibrate the BPro, as follows:
 - ▶ Press **Mode/Set** until the ABPM mode screen appears.
 - ▶ In ABPM mode, press and hold **+ / Std by** to enter the calibration mode. **POS** and **Std by** will appear.
 - ▶ Repeat steps 15 and 16 to complete the recalibration.



Flowchart for starting an ABPM session



Things to note during an ABPM session

1. The BPro will automatically trigger measurements at the preset interval and give off 3 alarm beeps 3 seconds before starting each measurement.
2. Whenever possible, keep the wrist still during each measurement until the measurement is complete.
3. The BPro will display the record number **rEC** (3, 4, 5, 6 ... 96) after each measurement.
4. If the BPro is unable to obtain a valid blood pressure reading, it will produce a long beep and then activate a second measurement cycle. If this second attempt fails again, it will activate a third measurement cycle.
5. The BPro has been programmed to repeat this 3-cycle sequence two more times, with an interval of one minute between sequences, if no valid readings are obtained.
6. If the BPro is unable to obtain valid blood pressure readings after a 3-cycle sequence, it will display **POS AdJ**. You will have one minute to adjust the sensor position before the next measurement cycle is activated. An event code is stored if a measurement is unsuccessful or errors are detected.

Information for patients

Introduction

This section is provided for the patient's use for ambulatory blood pressure monitoring applications.

Your doctor has selected the **BPro** ambulatory blood pressure monitor to measure your blood pressure for 24 hour period. The **BPro** is a convenient way to record blood pressure that looks like and is applied like a wrist watch. **BPro** allows you to continue with your normal activities while recording your blood pressure at regular time intervals.

What is ambulatory blood pressure monitoring (ABPM)?

Blood pressure is the force of the blood pushing against the walls of the arteries. Each time the heart beats it pumps blood into the arteries. Blood pressure is usually represented as SBP/DBP. Systolic blood pressure (SBP) is the pressure in your blood vessels when your heart contracts. Diastolic blood pressure (DBP) is the pressure in your blood vessels when your heart relaxes.

Your blood pressure may rise and fall in a natural rhythm during the day and night. Ambulatory blood pressure monitoring (ABPM) refers to the collection of the overall pattern of your blood pressure over a 24-hour period. Knowledge of your blood pressure pattern helps your physician to better understand and support your overall health.

The BPro divides the day and night bands as follows –

	Time (hrs)	Duration
Day band	0800-2000	12 hours
Night band	0000-0600	6 hours

The specified day and night bands are not user adjustable.

Precautions for using BPro

- **DO** keep the wrist still for about 12–15 seconds during measurements for optimal results. There will be 3 beeps to alert you just before a measurement cycle starts. Just relax, hold your wrist still, and breathe normally.
- **DO** try to keep a safe distance of 0.5 to 1 meter (1.6 to 3.3 ft) between the BPro and sources of electromagnetic radiation such as microwave oven, television or mobile phones when measuring blood pressure. For more details, refer to the manufacturer's EMC declaration in this manual.
- **DO NOT** apply the BPro to injured or irritated skin. Contact your physician if you experience any skin problem.
- **DO NOT** engage in any vigorous activity during the ABPM session.
- **DO NOT** subject the BPro to extreme temperatures, humidity or direct sunlight.
- **DO NOT** immerse the BPro in water. The BPro is mildly water-resistant (IPX2). Use a dry cloth to wipe the BPro if it gets wet.
- **DO NOT** set or reset the time or any ABPM settings during the monitoring period.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician or any other licensed healthcare practitioner.

Removing the BPro temporarily

It is recommended that you do not remove the BPro during the 24-hour session, and to sponge your body clean instead of bathing or showering. However, if you have to remove the BPro for any reason, please take care to strap it back in the original location. Please also note the removal and replacement in the activity log below.

Activity log

You are advised to keep a log of your activities during the ABPM session, such as the following:

- What medications you took and when you took them
- When you took your meals
- When you removed the BPro from your wrist and when you strapped it back
- What physical or mental activities you were engaged in when measurements were being taken
- When you slept and when you woke up

This log will help your physician interpret the ABPM data. You may use the log format shown on the next page.

[illegible]

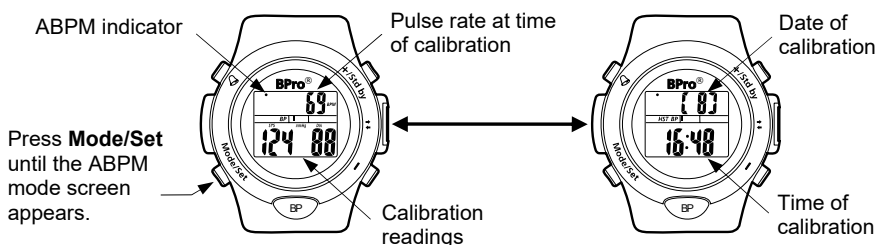
Terminating an ABPM session

The ABPM indicator (dot) at top left corner of the LCD screen indicates that an ABPM session is progress. It will disappear once the session is completed or terminated. The ABPM session will stop automatically after 24 hours.

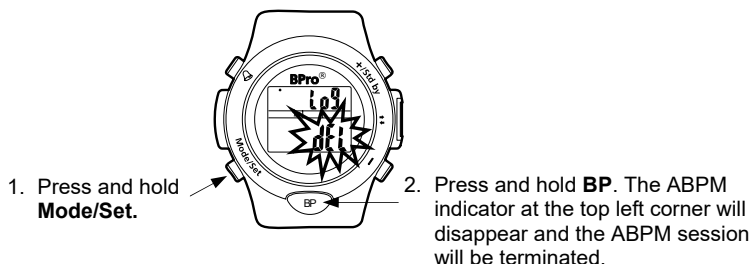
To terminate an ABPM session before it is completed, you can simply remove the BPro from the wrist and put it aside. The BPro will continue to attempt to take measurements even though it has been removed. It will beep during these attempts but you can simply ignore the beeps. If you do not wish to be disturbed by the beeps, complete the steps below. Either way, the data that have already been captured will be retained by the BPro.

Step 1

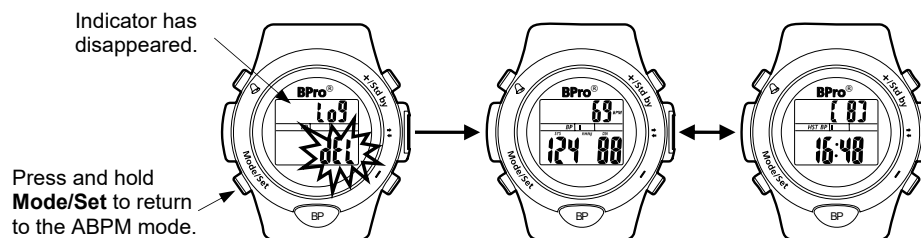
Select the ABPM mode. The display will switch between the calibration readings and the time of calibration.



Step 2



Step 3



After an ABPM session

Downloading ABPM data to a computer

Step 1

Install the BProSOft software on a computer. Refer to the BProSOft user manual for detailed instructions.

Step 2

Plug the USB connector of the BPro USB data cable into a USB port of the computer.

Step 3

Snap the cap at other end of the cable onto the BPro, as follows:



a) Lift up the latch on the cap of the BPro USB data cable. Align the 3 contact pins with the communications port by holding the cap at a slight angle off the BPro's face.



b) Press the cap against the face of the BPro. Ensure that the cap is flushed with the BPro.



c) Push down the latch to secure the cap to the BPro.



d) A click sound will be heard once the cap is latched properly. The latch will flush with the rim of the cap.

Step 4

If necessary, activate or re-activate the BPro. Refer to the BProSOft user manual for detailed instructions.

Step 5

Press the **Mode/Set** button to select **PC Conn** mode.

Step 6

Start the BProSOft software and click the **Download** icon.

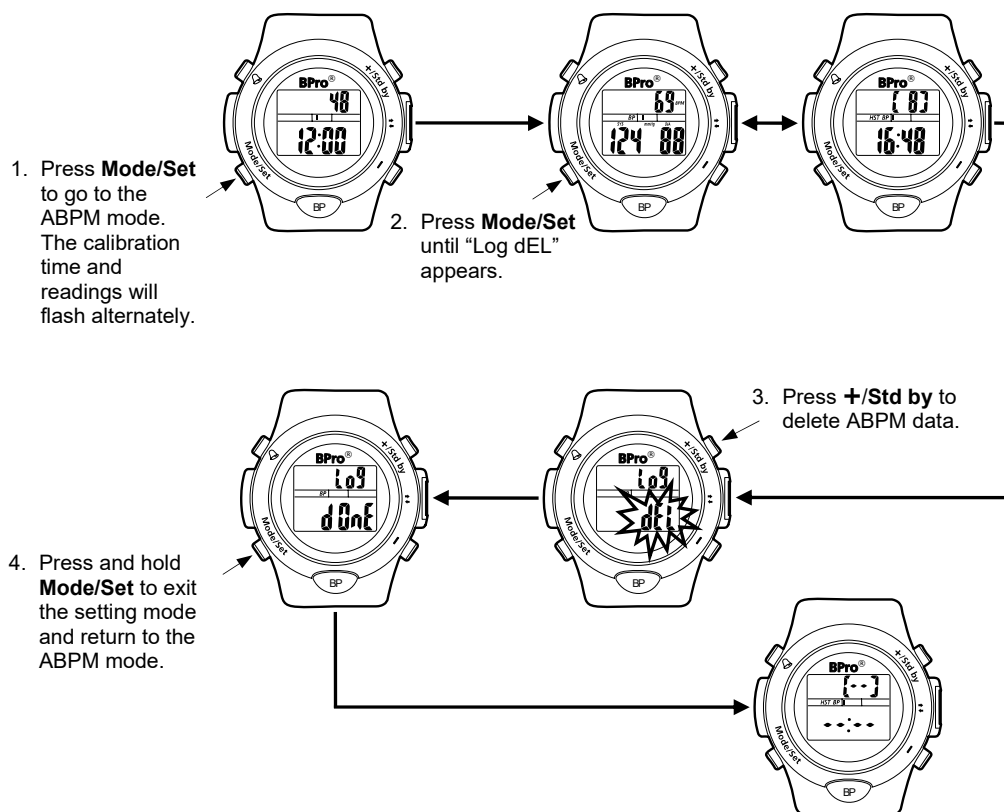
Step 7

Close the dialog box once the download is complete.

Note: Refer to the BProSOft user manual for complete instructions on downloading ABPM data to a computer, data analysis, data storage and report generation.

Deleting ABPM data

Complete the following sequence to delete all ABPM data:



The ABPM data are now deleted and the BPro is ready for the next ABPM session.

Maintenance and servicing

Battery replacement



1. Insert a coin of an appropriate size into the slot as shown.



2. Turn the battery cover with the coin in an anticlockwise direction until the cover pops out.



3. Remove the battery and insert a new one. Ensure that the positive polarity ("+" sign) is facing up.



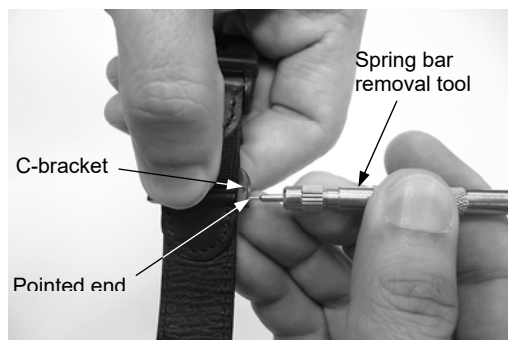
4. Put back the cover and using the coin, turn it in a clockwise direction until it locks.

Note: Remember to reset the time after every battery change.

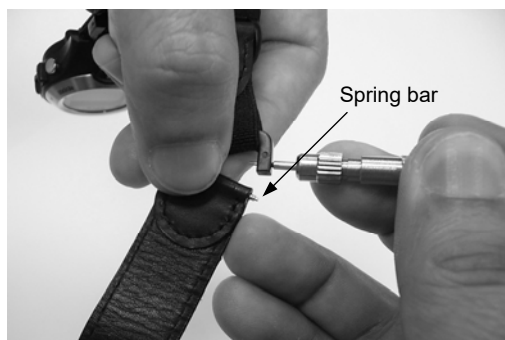


1. The BPro will not operate properly if the battery is not properly installed.
2. Use only a CR2032 3 V lithium coin-cell battery.

Strap removal

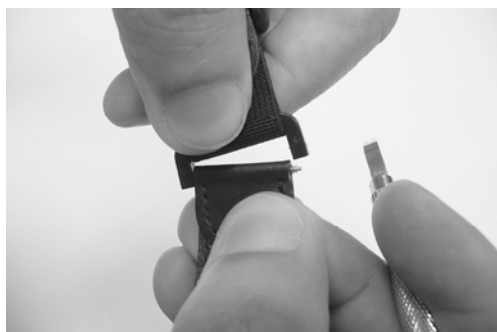


1. Insert the pointed end of the strap changing tool into one of the C-bracket holes holding the spring bar.

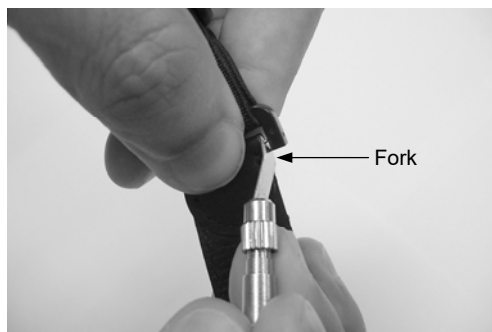


2. Push in the tip of the tool and gently pull the strap away from the end of the C-bracket.

Strap installation



1. Insert one end of the spring bar diagonally into one of the C-bracket holes.



2. Insert the fork of the strap changing tool onto the top end groove of the spring bar and press it down. Slowly move the bar into position and then release the fork. A click sound will be heard if the spring bar locks into position with the hole of the C-bracket. Give the strap a gentle pull. If the spring bar does not dislodge, it means that the strap has been properly installed.

Cleaning the BPro

The BPro LCD housing and parts may be wiped with a clean, moist cloth to remove surface grime. It is recommended to clean the patient contact surfaces between use by different patients to maintain hygiene. The following method is recommended.

Cleaning agents

- ASEPTI-zyme® (ECOLAB Inc.) or equivalent enzymatic cleaner
- TRIAD® medium alcohol prep pad (70% isopropyl alcohol pad or equivalent)

Cleaning steps

Clean and disinfect the BPro patient contact surfaces including the back case cushion, straps, sensor case cushion, and plunger, as follows.

1. Wipe the surfaces thoroughly with a cotton wool moistened with ASEPTI-zyme cleaning solution.
2. Wipe the surfaces thoroughly with a clean cotton wool moistened with clean water to remove ASEPTI-zyme.
3. Disinfect and wipe the BPro with an alcohol prep pad. Allow to air dry before use.

Note: Do not allow moisture to enter the LCD or sensor housing during any of the above steps.

Illustrations

Cleaning the LCD housing and sensor housing



1. Wipe with clean cotton wool moistened with ASEPTI-zyme.



2. Wipe with clean cotton wool moistened with clean water to remove ASEPTI-zyme.

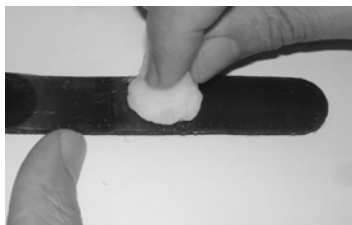


3. Disinfect with isopropyl alcohol prep pad and air dry.

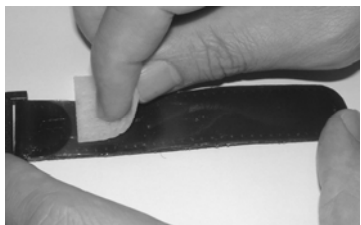
Cleaning the strap



1. Wipe with clean cotton wool moistened with ASEPTI-zyme.



2. Wipe with clean cotton wool moistened with clean water to remove ASEPTI-zyme.



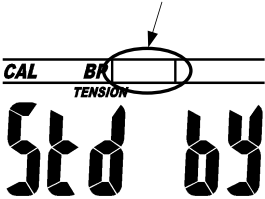
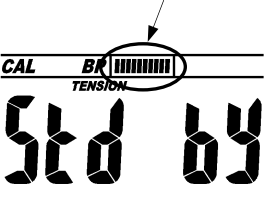
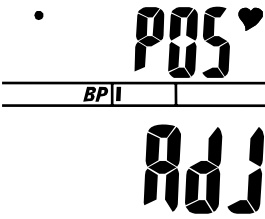
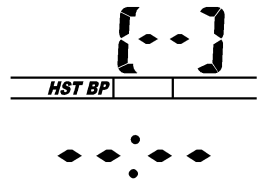
3. Disinfect with isopropyl alcohol prep pad and air dry.


Servicing

The BPro is not serviceable by the user. If you encounter any technical problem with the BPro, please contact HealthSTATS or an authorized agent.

The pressure sensor of the BPro has to be tested every two years to ensure correct functioning and accuracy of the device. Contact HealthSTATS or an authorized agent for details.

Troubleshooting guide

Description	Possible cause	Corrective action
<p>No pulsation bar</p> 	<p>Sensor not in ideal position to take readings.</p>	<p>a) Adjust the sensor so that the plunger rests on the spot with the strongest pulsations (refer to the section "Mounting the BPro on the patient").</p> <p>b) If the problem persists, please contact HealthSTATS or an authorized agent.</p>
<p>Full bar, non-pulsating</p> 	<p>Signal over-saturation. You may have strapped the BPro too tightly.</p>	<p>a) Loosen or re-strap your BPro (refer to the section "Mounting the BPro on the patient").</p> <p>b) Give the plunger a light tap to dislodge any particle that may have hindered its movement.</p> <p>c) If the problem persists, please contact HealthSTATS or an authorized agent.</p>
	<p>a) You may have moved your wrist while readings were being taken.</p> <p>b) Your BPro may have shifted position since the last BP measurement.</p>	<p>Keep your wrist still during measurements. Re-adjust or re-strap your BPro (refer to the section "Mounting the BPro on the patient").</p>
	<p>No existing historical BP records.</p>	<p>Records are available only when you have successfully calibrated your BPro and taken BP readings.</p>

	Low-battery level.	Replace with new battery.
Blank LCD	Battery is flat.	Replace with new battery.

Safety and accuracy of the BPro

Electrical safety

The BPro has been tested to meet the electrical and electromagnetic safety requirements of the following standards:

- IEC 60601-1 Medical electrical equipment. General requirements for safety.
- IEC 60601-1-1 Medical electrical equipment. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems.
- IEC 60601-1-2 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility. Requirements and tests.

Refer also to the section “Manufacturer’s EMC declaration”.

Accuracy

The BPro fulfills the provisions of the EC directive 93/42/EEC (Medical Device Directive) and conforms to the requirements of European and USFDA standards on noninvasive sphygmomanometers, in particular, the Requirements and test for non-automated measurement type and the Supplementary requirements for electromechanical blood pressure measuring systems. Refer to specifications for the standards.


The BPro has been clinically validated on subjects with the following blood pressure distribution:

	Range	Percentage of patients	ANSI/AAMI/EN/ISO 81060-1 minimum requirements
Systolic blood pressure	> 160 mmHg	16.9%	10%
	< 100 mmHg	10.1%	10%
Diastolic blood pressure	> 100 mmHg	12.4%	10%
	< 60 mmHg	10.1%	10%

The arm circumferences of the subjects ranged from 20 to 48 cm (7.9 to 18.9 in.). The wrist circumferences ranged from 13 to 21 cm (5.1 to 8.3 in.).

Manufacturer's EMC declaration

Manufacturer's declaration — electromagnetic emissions		
The BPro is intended for use in the electromagnetic environment specified below. The customer or the user of the BPro should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment (guidance)
RF emissions: CISPR 11	Group 1	The BPro uses RF energy only for its internal functions. Therefore, RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions: CISPR 11	Class B	The BPro is suitable in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes. The BPro is suitable for use with approved BP calibrators, the BProSoft 24-hour ABPM application software, and approved accessories. It is not suitable for interconnection with other equipment.

Manufacturer's declaration — electromagnetic immunity			
The BPro is intended for use in the electromagnetic environment specified below. The customer or the user of the BPro should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment (guidance)
Electrostatic discharge (ESD): IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV ±8 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Magnetic field power frequency: 50/60 Hz Magnetic field: IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF: IEC 61000-4-6	10 V _{RMS} : 150 kHz to 80 MHz 10 V/m for life-supporting: 150 kHz to 80 MHz inside ISM bands	10 V	Portable and mobile communications equipment should be used no closer to any part of the BPro, including cables, than the recommended separation distance, d , calculated from the equation applicable to the frequency of the transmitter, as follows: $d = (3.5/10)\sqrt{P}$ meters
Radiated RF: IEC 61000-4-3	10 V/m: 80 MHz to 2.5 GHz 10 V/m for life-supporting	10 V/m	$d = (3.5/10)\sqrt{P}$ meters for 80 MHz to 800 MHz $d = (7/10)\sqrt{P}$ meters for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 

Manufacturer's declaration — electromagnetic immunity
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NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
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NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<p>^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BPro is used exceeds the applicable RF compliance level above, the BPro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BPro.</p>
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<p>^bOver the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>
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Specifications

General	
Model	T6200 series
Display	LCD, 20 x 15 mm, 2 lines
Power source	CR 2032 3-volt lithium coin-cell battery
Battery life	1 to 6 months depending on usage
Control buttons	<ul style="list-style-type: none"> ▪ Mode/Set ▪  ▪ +/Std by ▪ — ▪ BP
Display	
Ambulatory blood pressure monitoring (ABPM) mode	<ul style="list-style-type: none"> ▪ Systolic pressure in mmHg ▪ Diastolic pressure in mmHg ▪ Pulse rate in beats/minute
Pulse wave analysis (PWA) mode	Pulsation bar
Memory (for ABPM)	96 blocks of waveform
Blood Pressure Measurement	
Measurement method	Modified applanation tonometry
Measurement site	Radial artery at the wrist (left or right)
Calibration method	Oscillometric, performed before use
Measurement time (for ABPM)	8 seconds per block of waveform
Blood pressure range	40 to 280 mmHg
Pulse rate range	30 to 180 beats/minute
Dimensions and Weight	
Watch head	44 [W] x 51 [L] x 19 [H] mm
Sensor housing	32 [W] x 38 [L] x 16 [H] mm
Weight	Approximately 50 grams with battery
Others	
Operating conditions	<ul style="list-style-type: none"> ▪ 10 to 40° C ▪ 15% to 90% relative humidity (non-condensing) ▪ 80 to 106 kPa atmospheric pressure
Storage conditions	<ul style="list-style-type: none"> ▪ -20 to 50° C ▪ 10% to 95% relative humidity (non-condensing)
Fastening straps	<ul style="list-style-type: none"> ▪ Fastening strap, 95 mm (3.7 in.), for wrist circumferences 130 to 150 mm (5.1 to 5.9 in.) ▪ Fastening strap, 125 mm (4.9 in.), for wrist circumferences 150 to 170 mm (5.9 to 6.7 in.) ▪ Fastening strap, 155 mm (6.1 in.), for wrist circumferences 170 to 210 mm (6.7 to 8.3 in.) ▪ Fastening strap, 185 mm (7.3 in.), for wrist circumferences 210 and larger (7.3 in. and

	larger) <i>Note: Straps not included in the components list can be purchased separately.</i>
Regulatory compliance	<ul style="list-style-type: none">■ Performance ANSI / AAMI / EN / ISO 81060-1■ Safety IEC 60601-1 IEC 60601-1-2 IEC 60601-2-30■ Environmental MIL-STD-810F (2000) IEC 60068-2-6 IEC 60068-2-27 IEC 60068-2-64 EN 60529

Note: The above specifications are subject to change without notice.

*The BPro may not meet its accuracy specifications if stored or operated outside the specified temperature and humidity ranges.

Option to select other similar devices

Alternative devices similar to the BPro are available in most markets. Users are advised to check the specifications of alternative devices.

Residual risk evaluation

Possible threat through residual risks	Means to risk avoidance/reduction	Risk Acceptability
Re-and/or cross infection; Inability to maintain hygiene safety	Patient contact surfaces can be disinfected. User instructions describe cleaning/disinfection.	acceptable
Inadequate labeling; inadequate specification of pre-use checks	Device labeling lists pre-use check of device, calibrator, cuff, serial cable, and battery.	acceptable

Replaceable consumable components

No.	Part Description	Part Number
1	Sensor Cushion	P3604A
2	Leather fastening strap, 95 mm	P3503A
3	Leather fastening strap, 125 mm	P3505A
4	Leather fastening strap, 155 mm	P3504A
5	Leather fastening strap, 185 mm	P3509A

Glossary

- Blood pressure (BP)** Sometimes referred to as **arterial blood pressure**, is the pressure exerted by circulating blood upon the walls of blood vessels, and is one of the principal vital signs.
- Diastolic pressure** It is the pressure that is exerted on the walls of the various arteries around the body in between heart beats when the heart is relaxed.
- Systolic pressure** It measures the amount of pressure that blood exerts on arteries and vessels while the heart is beating.

